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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,561	10/15/2004	David J. Chen	LBNL-201-US	4182

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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,561	CHEN ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-45* is/are pending in the application.

4a) Of the above claim(s) *23-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 19-45 are pending.

2. Applicant's election of Group I (claims 19-22) drawn to an antibody that specifically binds to an epitope defined by at least 10 amino acid sequence from human DNA-PKcs in the reply filed on 6/11/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Moreover, newly submitted claims 42-45 are directed to an invention that does not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13,2, they lack the same or corresponding special technical features. As discussed in the restriction requirement mailed 3/12/07, the inventions were found to have no special feature that defined the contribution over the prior art of Jafri et al. (Journal of Immunological Methods, vol. 251, p. 52-61, of record).

Accordingly, claims 23-45 are withdrawn from the consideration as being directed to a non-elected invention. See 37 CFR 1.142(b).

Claims 19-22 are under consideration.

3. Applicants' claim for domestic priority under 35. U.S.C.119(e) is acknowledged.

However, the provisional application upon which priority is claimed fails to provide adequate written support under 35. U.S.C. 112 for claims 19 and 22 of this application. The provisional application does not provide written support for " epitope defined by at least a ten amino acid sequence" as recited in claim 19 or "pT2609mAb" as in claim 22. Therefore, the effective filing date of the instant claims is deemed to be 4/21/03.

4. Applicants' submission of IDS filed on 10/15/04 is acknowledged. However, as Applicants failed to provided non-patent literatures as disclosed in the IDS filed 10/15/04, those references have not been considered and crossed out.

5. The use of trademarks has been noted in this application (e.g. HuMab-Mouse® on p.13, QuikChange® on p. 22). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent application, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 19 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter; a product of nature.

Claim 19 as written, does not sufficiently distinguish over antibody as is exists naturally because the claim do nesot particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 19 recites a phrase, "epitope defined by at least a ten amino acid sequence from human DNA-PKcs, said sequence comprising a phosphorylated threonine at position T2609".

It is not clear if the epitope is derived from multiple human DNA-PKcs homologs which share a conserved phosphorylated threonine at position 2609, at least 10 amino acid residues from any region of human DNA-PKcs with a phosphorylated threonine at 2609 or the 10+ amino acid residues comprising phosphorylated T2609 of human DNA-PKcs.

B) Claim 22 is indefinite in the recitation of pT2609mAb because its characteristics are not known. The use of pT2609mAb as the sole means of identifying the claimed antibody renders the claims indefinite because pT2609mAb is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct antibody. Moreover, pT2609mAb may also mean other biochemical molecules such as plasmid expressing T2609mAb as the recitation of "p" indicates plasmid in the field.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The monoclonal antibody pT2609mAb is essential to the claimed invention. The reproduction of the monoclonal antibody is an extremely unpredictable event. The monoclonal antibody pT2609mAb must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the monoclonal antibody and it is not apparent if the monoclonal antibody is readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the monoclonal antibody has been deposited under the Budapest Treaty **and that the hybridomas/antibodies will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808**. Further, the record must be clear that the

deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the antibody described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 19 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Chan et al. (Genes and Development, 2002, vol. 16, p. 2333-2338).

Chan et al. teach the polyclonal and monoclonal antibodies that specifically bind to an epitope comprising T2609 of human DNA-PKcs (p. 2333-2334, Fig 1.,2337, antibody, in particular). Chan et al, further teach that the T2609 of human DNA-PKcs is an autophosphorylation site (introduction, abstract, in particular) and said antibody does not bind to unphosphorylated T2609 is an inherent property as T2609 is always phosphorylated by the DNA-PK enzyme. Therefore, the reference teachings anticipate the claimed invention

14. Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Jafri et al. (Journal of Immonological Methods, vol. 251, p. 52-61, of record, provided 3/12/07) as is evidenced in LabVision DNA-PKcs Ab-1 datasheet (of record, provided 3/12/07)and in further evidence of Chan et al. (Genes and Development, 2002, vol. 16, p. 2333-2338).

Jafri et al. teach the monoclonal antibody to DNA-PKcs, clone 18-2 (p. 54, in particular). As is evidenced by the Datasheet provided from LabVision, the DNA-PKcs, clone 18-2 encompasses T2609. As is further evidenced by Chan et al., threonine at 2609 of human DNA-PKcs is autophosphorylated, said antibody does not bind to unphosphorylated T2609 is an inherent property as T2609 is always phosphorylated by the DNA-PK enzyme. Therefore, the reference teachings anticipate the claimed invention of claims 19-21 and 23-25.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. (Genes and Development, 2002, vol. 16, p. 2333-2338) or Jafri et al. (Journal of Immonological Methods, vol. 251, p. 52-61) as is evidenced in LabVision DNA-PKcs Ab-1 datasheet and in further evidence of Chan et al. (Genes and Development, 2002, vol. 16, p. 2333-2338) in view or U.S. Pat. No. 4,744,982..

The teachings of Chan et al. or Jafri et al and the evidentiary references have been discussed, supra.

The Chan et al. and Jafri et al. references do not teach human monoclonal antibody.

However, the '982 patent teaches human monoclonal antibody is desired because the human monoclonal antibody avoids the cross reaction of polyclonal antibody and provides precise antibody for rapid diagnosis and endless supply of antibody (col. 1-2, overlapping paragraph, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to make human monoclonal antibody as taught by the '982 patent with the antibody to DNA-PKcs as taught by Chan et al. or Jafri et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the human monoclonal antibody taught by the '982 patent avoids the cross reaction of polyclonal antibody and provides precise antibody for rapid diagnosis and endless supply of antibody.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. No claims are allowable.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
August 20, 2007

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600